MAR 2 0 2013

K123403

510(k) Summary
AxSOS Locking Plate System

Proprietary Name:	AxSOS Locking Plate System
Common Name:	Bone plates
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Regulatory Class:	Class II
Product Codes:	87 HRS: Plate, Fixation, Bone
Predicate Devices:	AxSOS Locking Plate System Stryker Plating System
For Information contact:	John DeMauro, Regulatory Affairs Consultant Stryke Trauma AG Bohnackerweg 1 CH-2545 Selzach Switzerland Phone: (201) 831-5804 Fax: (201) 831-4804 john.demauro@stryker.com
Date Prepared:	November 2, 2012

Description

This Special 510(k) submission is a line extension to address modifications made to the AxSOS Locking Plate System which was cleared in K061012. This line extension is to add tibia long plates to the existing size range of the AxSOS Locking Plate System. These monoaxial long plates will be known as AxSOS Proximal Lateral Tibia Long Plates and will be available in four length sizes in left and right configurations.

Intended Use

The AxSOS Locking Plate System is intended for use in long bone fracture fixation.

Indications

The AxSOS Locking Plate System is intended for use in long bone fracture fixation. The system is indicated for fixation of long bone fractures including but not limited to fractures of the humerus, tibia and femur.

Substantial Equivalence

The AxSOS Proximal Lateral Tibia Long Plates are substantially equivalent to the AxSOS Proximal Lateral Tibia Plates of the AxSOS Locking Plate System cleared under K061012 and to the Proximal Lateral Tibia Plates of the Stryker Plating System (SPS) cleared under K050512 in regards to intended use, design, materials, and operational principles as a bone fixation device.

Summary of Non-Clinical Testing and Evaluation

Risk analysis was performed according to the requirements of ISO 14971:2007 "Medical Devices-Application of risk management to medical devices." Records of the risk analysis process are retained in the design history file. Testing has been performed as per ASTM F382-99 to demonstrate equivalence of the subject device to its predicate device. Finite Element Analysis (FEA), was used to identify the worst case for plate loading. Static strength testing using axial compression was performed. Fatigue strength testing was conducted using axial loading. Results were used to evaluate median fatigue limits and dynamic stiffness, therefore substantiating equivalence to the comparative proximal lateral tibia plates of the Stryker Plating System cleared under K050512.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 20, 2013

Stryker Trauma AG
% Howmedica Osteonics Corporation
Ms. Estela Celi
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K123403
Trade/Device Name: AxSOS Proximal Lateral Tibia Long Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: March 1, 2013
Received: March 4, 2013

Dear Ms. Celi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

Indications for Use

510(k) Number (if known):

Device Name: AxSOS Proximal Lateral Tibia Long Plates

Indications for Use:

The AxSOS Locking Plate System is intended for use in long bone fracture fixation. The system is indicated for fixation of long bone fractures including but not limited to fractures of the humerus, tibia and femur.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Divison of Orthopedic Devices